

Claims

1. An amorphous form of olanzapine.
- 5 2. An amorphous form of olanzapine as claimed in claim 1, wherein the olanzapine is in particulate form.
3. An amorphous form of olanzapine as claimed in claim 1 or 2, wherein the olanzapine is substantially pure.
- 10 4. An amorphous form of olanzapine as claimed in any one of claims 1 to 3, having an IR spectrum substantially as shown in Figure One, an XRPD spectrum substantially as shown in Figure Two, and/or a DSC trace substantially as shown in Figure Three.
- 15 5. An amorphous form of olanzapine as claimed in any one of claims 1 to 4, for use as a medicament.
6. A process for the preparation of an amorphous form of olanzapine as
20 claimed in any one of claims 1 to 5, comprising the step of melting one or more crystalline forms of olanzapine.
7. A process as claimed in claim 6, further comprising the step of cooling the melt.
- 25 8. A process for the preparation of an amorphous form of olanzapine as claimed in any one of claims 1 to 5, comprising the step of freeze-drying or spray-drying a solution comprising olanzapine.
- 30 9. A process as claimed in claim 8, wherein the solution further comprises water or an alcohol or a mixture thereof.

10. A process for the preparation of an amorphous form of olanzapine as claimed in any one of claims 1 to 5, comprising the step of forming a solid solution comprising olanzapine and an excipient.
- 5 11. A process as claimed in claim 10, wherein the excipient is lactose, povidone or crospovidone.
12. A method of preparing a pharmaceutical composition, comprising utilising an amorphous form of olanzapine as claimed in any one of claims 1 to 5.
- 10 13. A method as claimed in claim 12, wherein the pharmaceutical composition is for oral or parenteral administration.
14. A method as claimed in claim 12 or 13, wherein the pharmaceutical
15 composition is a tablet or capsule for oral administration.
15. A method as claimed in claim 12 or 13, wherein the pharmaceutical composition is a solution for oral or parenteral administration.
- 20 16. A pharmaceutical composition, comprising an amorphous form of olanzapine as claimed in any one of claims 1 to 5.
17. A pharmaceutical composition as claimed in claim 16, further comprising a pharmaceutically acceptable carrier, excipient or diluent.
- 25 18. A pharmaceutical composition as claimed in claim 16 or 17, wherein the composition is for oral or parenteral administration.
19. A pharmaceutical composition as claimed in any one of claims 16 to 18,
30 wherein the composition is in the form of a tablet or capsule for oral administration or in the form of a powder suitable for preparing a solution for oral or parenteral administration.

20. A pharmaceutical composition as claimed in claim 19, wherein the composition is in the form of a tablet or capsule and further comprises lactose, hydroxypropylcellulose, crospovidone, microcrystalline cellulose, magnesium stearate, gelatine and/or mannitol.

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21. A pharmaceutical composition as claimed in claim 19, wherein the composition is in the form of a powder and further comprises lactose, tartaric acid, hydrochloric acid and/or sodium hydroxide.

10 22. A pharmaceutical composition as claimed in any one of claims 16 to 21, wherein the composition is in unit dosage form comprising from 1mg to 30mg amorphous olanzapine.

15 23. A pharmaceutical composition as claimed in any one of claims 16 to 22, for the treatment of a psychiatric, psychological or psychotic disorder, an anxiety disorder, or a gastrointestinal or functional bowel disorder.

20 24. A pharmaceutical composition as claimed in claim 23, wherein the psychiatric, psychological or psychotic disorder is schizophrenia, schizophreniform disorder, schizoaffective disorder, Tourette's disorder, mania, manic episode, severe manic episode, delusional disorder, psychotic disorder, psychosis, bipolar disorder, depression, or a disorder of the central nervous system.

25 25. A pharmaceutical composition as claimed in claim 24, wherein the psychiatric, psychological or psychotic disorder is schizophrenia, manic episode, severe manic episode, psychosis, or bipolar disorder.

30 26. A pharmaceutical composition as claimed in claim 23, wherein the anxiety disorder is generalised anxiety disorder, obsessive-compulsive disorder, post-traumatic stress disorder, or an anxiety state.

27. A pharmaceutical composition as claimed in claim 23, wherein the gastrointestinal or functional bowel disorder is irritable bowel syndrome, gastric

hypermotility, ichlasia, hypertonic lower esophageal sphinctor, tachygastria, constipation, diarrhoea, mucorrhoea, or pain or discomfort over the course of the sigmoid colon.

5 28. A method of treating a condition selected from a psychiatric, psychological or psychotic disorder, an anxiety disorder, or a gastrointestinal or functional bowel disorder, comprising administering an effective amount of an amorphous form of olanzapine as claimed in any one of claims 1 to 5, an effective amount of a pharmaceutical composition prepared by a method as claimed in any one of claims
10 12 to 15, or an effective amount of a pharmaceutical composition as claimed in any one of claims 16 to 27, to a patient in need thereof.

29. A method as claimed in claim 28, wherein the patient is a human.

15 30. A method as claimed in claim 28 or 29, wherein the amount of an amorphous form of olanzapine administered is from 2mg to 20mg per day.

31. A method as claimed in any one of claims 28 to 30, wherein the psychiatric, psychological or psychotic disorder is schizophrenia, schizophreniform disorder,
20 schizoaffective disorder, Tourette's disorder, mania, manic episode, severe manic episode, delusional disorder, psychotic disorder, psychosis, bipolar disorder, depression, or a disorder of the central nervous system.

32. A method as claimed in claim 31, wherein the psychiatric, psychological or
25 psychotic disorder is schizophrenia, manic episode, severe manic episode, psychosis, or bipolar disorder.

33. A method as claimed in any one of claims 28 to 30, wherein the anxiety
30 disorder is generalised anxiety disorder, obsessive-compulsive disorder, post-traumatic stress disorder, or an anxiety state.

34. A method as claimed in any one of claims 28 to 30, wherein the gastrointestinal or functional bowel disorder is irritable bowel syndrome, gastric

hypermotility, ichlasia, hypertonic lower esophageal sphinctor, tachygastria, constipation, diarrhoea, mucorrhoea, or pain or discomfort over the course of the sigmoid colon.